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| EXAMINER HOPKINS, CHRISTINE D | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/673,661

Applicant(s)

ERIKSSON ET AL.

Examiner

CHRISTINE D. HOPKINS

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 32-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 26 January 2009. Claims 21-40 are now pending. Claims 32-40 remain withdrawn. The Examiner acknowledges the amendments to claims 21-25 and 29.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 21-23 and 25-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonutti (U.S. Patent No. 7,134,437). Bonutti discloses a tissue removal apparatus comprising a flexible drill shaft. Regarding claim 21, Bonutti teaches a dermal tissue harvester assembly including: a housing **18** with a port; a rotatable shaft **14**; a tissue cutting tool **16** mounted on the shaft, and capable of cutting dermal tissue, wherein the cutting tool is received within an opening in the housing; and an electric motor **20** coupled to a power source and the rotatable shaft, wherein the cutting tool is configured to rotate within the opening (col. 5, lines 37-48); a tissue particle collector **28**; a nanograft cell **172**; and a particle retriever (cannula/curette assembly) (col. 9, lines 46-52) wherein the retriever is capable of being received by the port and injecting tissue

into the nanograft cell. With respect to claim 22, the suction line port leading to the housing **18** (Fig. 1) is interpreted as a "tissue opening" since the tissue is suctioned from the housing through the suction line **30**. This "tissue opening" is capable of serving as an orifice for pressing against and receiving a dermal tissue layer of a tissue source. Regarding claim 23, the cutting tool is configured such that it is capable of extending through the "tissue opening" and penetrating tissue. With respect to claim 25, the tissue particle retriever is considered to be a syringe since the cannula/curette assembly works to retrieve graft material (col. 9, lines 46-52).

Regarding claim 26, the cutting tool is configured as a rotary drum since a rotating motion is imparted on the drill shaft to move the cutting tip (col. 5, lines 37-48). With respect to claims 27 and 28, the cutting tool comprises a slot **123** extending along the rotary drum; the slot is parallel to the rotatable shaft; and further includes sharpened cutting elements such as cutting edges **126** (Fig. 14B), which form a serrated blade. With respect to claims 29 and 30, it is unclear what an "end mill type" cutting tool is, therefore Fig. 14A is found to anticipate the claims since a tapered cylinder tip **120** is located on the end of the cutting tool (Figs. 14A and 14B).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 24 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (U.S. Patent No. 7,134,437). Regarding claim 24, Bonutti discloses the invention as claimed, see rejection supra; however Bonutti does not disclose expressly that the cutting tool is configured to extend into the tissue in a range from approximately 0.01 mm to approximately 0.9 mm. Instead, Bonutti indicates that the cutting tool extends in the tissue to remove bone tissue, cartilage, muscle and fetal tissue (col. 2, lines 25-35). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to configure the cutting tool to extend into the tissue surface in a range from approximately 0.01 mm to approximately 0.9 mm because Applicant has not disclosed that such a range provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Bonutti's extended range of cutting into the bone, and applicant's invention, to perform equally well with either the range taught by Bonutti or the claimed approximately 0.01 mm to approximately 0.9 mm range because both would perform the same function of enabling cutting of dermal tissue. Therefore, at the time of the invention it would have been prima facie obvious to modify Bonutti to obtain the invention as specified in claim 24 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Bonutti.

Regarding claim 31, Bonutti discloses the invention as claimed, see rejection supra; however Bonutti does not disclose expressly that the port is a luer fitting. Instead, Bonutti indicates that the port leads to a suction line (Fig. 1). At the time the

invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a luer fitting because Applicant has not disclosed that a luer fitting provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Bonutti's port fitting to the suction line and applicant's invention, to perform equally well with either the port taught by Bonutti or the claimed luer fitting because both would perform the same function of enabling suction to be created through the port. Therefore, at the time of the invention it would have been prima facie obvious to modify Bonutti to obtain the invention as specified in claim 31 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Bonutti.

Response to Arguments

6. Applicant's arguments filed 26 January 2009 with respect to the objection to claim 24 have been fully considered and are persuasive. The objection to claim 24 has been withdrawn.

7. Applicant's arguments filed 26 January 2009 with respect to the rejection of claims 29 and 30 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 29 and 30 under 35 U.S.C. 112, second paragraph has been withdrawn.

8. Applicant's arguments filed 26 January 2009 with respect to the rejection of claims 21-23 and 25-30 under 35 U.S.C. 102(e) citing Bonutti ('437) have been fully considered but are not persuasive. Applicant contends that Bonutti does not disclose a cutting tool received within an opening of the housing. The cutting tool is capable of being "received" within an opening in the housing. The claim does not require that the cutting tool is attached to, or connected with, an opening in the housing.

Applicant further contends that the Bonutti device is not a 'dermal tissue nanografting system," and instead, all work performed with the Bonutti device is performed percutaneously through the surface of the dermal tissue. However, this argument is not persuasive. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The device of Bonutti may be used for the removal of cartilage, muscle and fetal tissue (as noted by Applicant), and is therefore capable of cutting dermal tissue.

Applicant also contends that Bonutti does not disclose a housing with a port. However, this argument is not persuasive. The housing contains several ports as shown in Fig. 1 which lead to, for instance, elements **22**, **28**, **20**, and **14**. As an example, suction line **30** provides suction capabilities to **12** (col. 5, lines 53-55), therefore defining a port. In view of the foregoing, the rejection of claims 21-23 and 25-30 under 35 U.S.C. 102(e) citing Bonutti ('437) has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735